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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/624,530	07/24/00	SACKLER R	200.238US1C

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EXAMINER	
WELLS,L	
ART UNIT	PAPER NUMBER
1619	9

DATE MAILED: 10/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/624,530	Applicant(s) SACKLER ET AL.	
	Examiner Lauren Q Wells	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 6-23 are pending.

Response to Arguments

Applicant's arguments with respect to claims 6-23 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,478,577, over claims 1-14 of U.S. Patent No. 5,672,360, over claims 1-13 of U.S. Patent No. 6,143,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are drawn towards a method for treating pain for a time period of about 24 hours comprising a solid, controlled-release oral dosage form.

Claims 6-23 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 09/632,718, over claims 1-20 and 53-61 of copending Application No. 09/390,719, over claims

23-111 of copending Application No. 08/938,898, over claims 27-68 of copending Application No. 09/304,694. Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are drawn towards methods of treating pain for a time period or about 24 hours comprising a solid, controlled-release oral dosage form and/or an oral sustained release pharmaceutical dosage forming comprising an opiod analgesic and matrices components.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 6-16, 18 and 21-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (5,968,551).

Oshlack et al. teach orally administrable opiod formulations having an extended duration of effect. At least 24 hours is disclosed as the extended duration. Disclosed are beads with an opiod analgesic with an overcoat of a hydrophobic material, such as acrylic polymer, alkylcellulose and other polymers. Hydromorphone, morphine, oxycodone and others are disclosed as opiod analgesics. It is disclosed that 4-800mg of opiod analgesic can be

incorporated into the oral dose form. Spheroids are disclosed as a form of the composition. A preferred embodiment disclosed includes sustained release dosage forms comprising a plurality of substrates comprising an active ingredient, wherein the substrates are coated with a sustained release coating. Ethylcellulose is disclosed as a plasticizer, wherein the plasticizer and hydrophobic polymer are an aqueous dispersion making up the coating. Also disclosed are microparticulated sustained release matrices, wherein the matrix is comprised of hydrophilic polymers, long chain hydrocarbons and polyalkylene glycols. Ethylcellulose is disclosed as a hydrophilic polymer. See Col. 2, line 54-Col. 16, line 15; Col. 20, line 15-Col. 24, line 41.

Claims 6-15, 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Paradissis et al. (5,133,974).

Paradissis et al. teach extended release pharmaceutical formulations. A 24 hour time period is disclosed as the extended release. The formulation is disclosed as comprising an immediate release particle containing a drug, substrate and binder, coated with talc, and further coated with a dissolution modifying system containing plasticizers and a film forming agent. Analgesics disclosed include morphine, hydromorphone, and oxycodone. The drug adheres to an inert spherical substrate particle through a binding agent, which is applied by a solvent. Ethylcellulose, acrylic acid copolymers and methyacrylic acid copolymers are disclosed as binders. Water insoluble hydrophobic plasticizers disclosed include castor oil. Acrylic and methacrylic acid copolymers and cellulose derivatives are disclosed as film forming polymers. Amounts of at least 50mg per dosage form are disclosed. See Col. 4, line 26-Col. 8, line 26.

Claims 6-19 and 21-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (5,266,331).

Oshlack et al. teach a solid controlled release, oral dosage form, wherein the dosage form comprises oxycodone in a matrix. Other analgesics disclosed include hydromorphone and morphine. The oral dosage form is disclosed as providing at least 12 hours of pain relief. Spheroids are disclosed as a dosage form. 1-50mg is disclosed as a preferred dosage amount. Suitable matrix materials disclosed include hydrophilic polymers (gums, cellulose ethers, acrylic resins), long chain hydrocarbons and polyalkylene glycols. A preferred dosage form is disclosed as comprising a film coated spheroid containing active ingredient and a non-water soluble spheronising agent. It is further disclosed that the spheroids may also contain a binder, such as hydroxy alkyl celluloses and water insoluble polymers such as acrylates and ethyl celluloses. The spheroids are preferably film coated with a wax, shellac or zein, ethyl cellulose, or polymethylacrylate. See Col. 1, line 47-Col. 5, line 36.

Claims 6-13, 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (5,685,585)

Oshlack et al. teach a stabilized controlled release dosage form having a coating derived from an aqueous dispersion of ethylcellulose. Spheroids are disclosed as a form of the composition. Water-insoluble plasticizers are disclosed for use in the coating. Morphine, hydromorphone, and oxycodone are disclosed as therapeutic agents for use in the composition. See Col. 4, line 54-Col. 10, line 17.

Claims 6-8, 11-19, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldie et al. (4,844,909).

Goldi et al. teach a solid controlled release, oral dosage form comprising hydromorphone in a matrix. The effect of the oral dosage form is disclosed as at least 12 hours. Spheroids are

disclosed as a form. The oral dosage form comprises between 1 and 100 mg of opiod. Suitable matrix materials are hydrophilic or hydrophobic polymers (gums, cellulose ethers, acrylic resins), long chain hydrocarbons, and polyalkylene glycols. Ethyl cellulose is also disclosed as a suitable controlled release matrix. A normal release matrix is also disclosed, wherein the form comprises a film coated spheroids containing active ingredient and a non-water soluble spheronising agent. Ethyl cellulose and polymethacrylate are disclosed as film coats. See Col. 1, line 54-Col. 10, line 60.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al. in view of Oshlack et al. ('551) or Oshlack et al. ('331).

Goldie et al. fail to teach morphine, oxycodone, blood levels of hydromorphone (see above discussion).

Oshlack et al. and Oshlack et al. are discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Goldie et al. using the teachings of Oshlack et al. or Oshlack et al. and obtain an oral dosage form wherein morphine or oxycodone are the opiod analgesic because a) Goldie, Oshlack and Oshlack all teach orally administrable sustained

release opiod analgesics; b) Oshlack and Oshlack teach hydromorphone, morphine, and oxycodone as interchangeable and combinable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
September 24, 2001

DAMERON L. JONES
PRIMARY EXAMINER